IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC. and ENDO PAR INNOVATION COMPANY, LLC, *Plaintiffs*, v. ZYDUS PHARMACEUTICALS (USA) INC. AND ZYDUS LIFESCIENCES LTD., *Defendants*.	)	C.A. No. 23-866-JLH-LDH

PAR PHARMACEUTICAL, INC. AND ENDO PAR INNOVATION COMPANY, LLC'S NOTICE OF DEPOSITION OF DEFENDANT PURSUANT TO FED. R. CIV. P. 30(B)(6)

Pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs Par Pharmaceutical, Inc. and Endo Par Innovation Company, LLC (collectively, "Par"), by and through their attorneys, will take the deposition of Defendants Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd. (collectively, "Zydus"), by oral examination using live or remote videotape, audio tape, or stenographic means, or a combination of those means. The oral examination will begin at a time mutually agreed upon by the parties at the office of Dechert LLP, Cira Centre, 2929 Arch St. Philadelphia, PA 19104-2808. The examination will take place and continue from day to day until completed. The deposition will be before a Notary Public or other officer authorized by law to administer oaths.

Pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Zydus shall designate one or more officers, directors, managing agents, or other persons who consent and are knowledgeable to testify on its behalf with respect to each of the subject matters set forth in the attached Schedule A. Zydus is requested to provide Par's counsel with written notice, at least five

business days in advance of the deposition, of any and all documents and things that in any way refer to or concern any of the topics set forth in the attached Schedule A that have not been previously produced to Par in this action. Par reserves the right to continue this deposition should Zydus fail to produce such documents and things at or before the time of deposition.

Dated: July 12, 2024

Respectfully submitted,

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SCHEDULE A

DEFINITIONS

The definitions set forth in Par's First Set of Interrogatories to Zydus are incorporated by reference.

1. You," "your," "Zydus," "Zydus's," "Defendant," or "Defendant's" means Defendants Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd as well as all of their predecessors and successors, subsidiaries, divisions, assigns, parent corporations, and affiliates, and all past or present employees, officers, directors, partners, owners, members, agents, legal representatives, consultants, or other persons (including attorneys) acting for or on their behalf.

2. "Person" refers to any individual, corporation, proprietorship, association, joint venture, company, partnership, or other business or legal entity, including governmental bodies and agencies. The masculine includes the feminine and vice versa. The singular includes the plural and vice versa.

3. "License" means any authorization to make, have made, use or sell any product or process (i) the unlicensed manufacture, use or sale of which would infringe any United States or foreign patent, (ii) that is claimed in any United States of foreign patent application, or (iii) that is the subject of a trade secret, including but not limited to any agreement (whether in the form of a grant, sublicense, bilateral contract, option, offer to make a unilateral contract, stipulation in a legal action or other proceeding, statement that patent rights will not be asserted in respect of particular subject matter, or agreement to sell or distribute any patented product) and any schedule, addendum, or amendment thereto, and any modification thereof.

4. "NDA" means "New Drug Application" as defined under 21 U.S.C. § 355(b) *et seq*.

5. "ANDA" means "Abbreviated New Drug Application" as defined under 21 U.S.C. § 355(j).

6. "ANDA filer" means any person who files an Abbreviated New Drug Application with the U.S. Food & Drug Administration ("FDA")

7. The term "Par Varenicline Tartrate Products" refers to the products that are the subject of ANDA No. 201785, including any supplements and/or amendments thereto.

8. The term "varenicline tartrate tablets" means any pharmaceutical tablet product containing varenicline tartrate.

9. The term "API" means active pharmaceutical ingredient.

10. "Zydus ANDA" means Your ANDA No. 216723, including any supplements and/or amendments thereto.

11. "Zydus Varenicline Tartrate Products" means the drug products that are the subject of the Zydus ANDA.

12. The term "Patents-in-Suit" refers to U.S. Patent No. 11,717,524, entitled "Varenicline Compound and Process of Manufacture Thereof" and any applications which led to its issuance; U.S. Patent No. 11,779,587, entitled "Varenicline Compound and Process of Manufacture Thereof" and any applications which led to its issuance; and any other patents Par asserts are infringed via amendments to the complaint in this litigation.

13. "This action," "This action," "this lawsuit," or "this litigation" means *Par Pharmaceutical, Inc., et al. v. Zydus Pharms. (USA) Inc., et al.*, Civil Action No. 1:23-cv-866-RGA-LDH (D. Del.).

14. The term "prior art" refers to all publications, patents, disclosures, sales, offers for sale, prior inventions, admissions, or other acts or occurrences including within the meaning of

35 U.S.C. §§ 102 and/or 103, that Zydus contends constitute prior art to any of the Patents-in-Suit.

15. The singular form of any word appearing herein includes the plural, and the plural form of any word appearing herein includes the singular, except as otherwise expressly stated herein.

16. "Concerning," "referring to," and/or "relating to" mean the following: comprising, regarding, with regard to, pertaining to, mentioning, reflecting, in connection with, about, referring to, with reference to, evidencing, involving, describing, depicting, discussing, commenting on, embodying, responding to, supporting, refuting, contradicting, or constituting (in whole or part).

17. The term "considered" means the following: viewed, consulted, checked, referenced, confirmed, referred to, relied upon, taken into account, and/or taken into consideration.

18. The term "date" means the exact day, month, and year, if ascertainable, or if not, the best approximation (including relationships to other events).

19. "And" and "or" shall be construed either disjunctively or conjunctively as necessary to bring w/in the scope of the request all responses that might otherwise be construed to be outside of its scope.

20. "Document" and/or "documents" shall be given the broadest meaning permitted under the Federal Rules of Civil Procedure, and includes papers of all kinds and nonpaper information storage means, including by way of example and without limitation, originals and copies, however made, of letters, memoranda, notes, computer-generated data, calendars, records, minutes, studies, reports, notebooks, messages, telegrams, ledgers, legal instruments,

agreements, drawings, sketches, graphs, prints, hand-written notes, rough drafts, secretarial notes, work pads, diaries, films, tapes, videotapes, CDs, DVDs, pictures, photographs, books, pamphlets, publications, advertisements, sales literature, brochures, manuals, price lists, computer files, announcements, electronic mail messages, or any other writings, records, or tangible objects produced or reproduced mechanically, electrically, electronically, photographically, or chemically.

21. "Contact" or "communication" include, without limitation, every manner and means of statement, utterance, notation, disclaimer, transfer or exchange of information of any nature whatsoever, by or to whomever, whether oral or written or whether face-to-face, by telephone, mail, personal delivery or otherwise, including, but not limited to, letters, correspondence, conversations, memoranda, dialogue, discussions, meetings, interviews, consultations, agreements and other understandings.

TOPICS

1. The formulation of the Zydus Varenicline Tartrate Products, including but not limited to:

   a. The identity, amount, and function(s) of each ingredient in such products;

   b. The reasons for the selection and amount of each component in the Zydus Varenicline Tartrate Products;

   c. Any changes to the formulation of Zydus's Varenicline Tartrate Product during development or during FDA review to improve the impurity profile of Zydus's Varenicline Tartrate Products.

   d. All specifications for and other documents describing the properties, use, purpose, or function of the raw materials, ingredients, excipients, and component parts

contained in the Zydus Varenicline Tartrate Products.

2. The process for manufacturing the API used in the Zydus Varenicline Tartrate Products, including but not limited to:

   a. The location where Zydus or Zydus's affiliate manufactures the API used in Zydus's Varenicline Tartrate Product;

   b. The manufacturing processes used during the manufacture of the API used in Zydus's Varenicline Tartrate Product, including the process described in the manufacturing batch records, drug master files, or other portions of Zydus's ANDA

   c. The steps taken during the API manufacturing process to control impurities.

3. Impurity levels of the API used in the Zydus Varenicline Tartrate Products.

4. The packaging, labeling, and product inserts to be used with the Zydus Varenicline Tartrate Products, including the identity of the most current versions thereof.

5. The process for manufacturing the Zydus Varenicline Tartrate Products, including but not limited to:

   a. The location where Zydus or a Zydus affiliate manufactures Zydus's finished Varenicline Tartrate Product;

   b. The manufacturing processes used during the manufacture of Zydus's Varenicline Tartrate Product, including the process described in the manufacturing batch records relating to Zydus's Varenicline Tartrate Products,

   c. The manufacture of varenicline tartrate products made by Zydus or on Zydus's behalf at laboratory, validation, or pilot scale size, as well as all records relating to the manufacture and distribution thereof.

6. The analytical methods used by Zydus to detect and quantify impurities in Zydus's Varenicline Tartrate Products or the API used in Zydus's Varenicline Tartrate Products including but not limited to the analytical method's development and validation.

7. All specifications, including but not limited to in-process, release, and stability specifications, relating to the identity or amount of any impurities or potential impurities in Zydus's Varenicline Tartrate Products and the varenicline tartrate API used in Zydus's Varenicline Tartrate Products.

8. All testing conducted by Zydus on any varenicline tartrate products, including without limitation any Par Varenicline Tartrate Products, Zydus Varenicline Tartrate Products, and any prior art varenicline tartrate products as well as any test results and analyses thereof, whether carried out by you or by a third party on your behalf, including but not limited to:

a. Studies and/or testing referring to, memorializing, or characterizing any assay, stability, degradation product, or impurity data or other test results concerning the Zydus Varenicline Tartrate Products, the API in the Zydus Varenicline Tartrate Products, any other varenicline tartrate product, or the API in any other varenicline tartrate product;

b. Any varenicline-containing formulation considered, tested, selected, rejected, abandoned and/or manufactured by or for Zydus, including why each such varenicline tartrate product was considered, tested, selected, rejected, abandoned and/or manufactured;

c. All testing or analyses performed comparing a varenicline tartrate product against any other varenicline tartrate product that has been or is currently being marketed;

d. Any testing and/or deformulation of any varenicline tartrate products.

9. The identity of all persons, including any third parties, involved in the research and development of the Zydus Varenicline Tartrate Products and the role that each such person had in connection therewith.

10. The preparation, filing, and attempts to secure FDA approval of the Zydus Varenicline Tartrate Products, including but not limited to:

a. The identity and contents of Zydus's ANDA particularly with respect to the manufacture, composition, and impurities in the Zydus Varenicline Tartrate Products and Zydus's communications with the FDA regarding the same;

b. The identity and contents of Zydus's ANDA particularly with respect to the manufacture, composition, and impurities in the API used in Zydus Varenicline Tartrate Products and communications with the FDA regarding the same;

c. All communications between Zydus and the FDA relating to Zydus's ANDA and supplements or amendments thereto, including those related to the approval of Zydus's ANDA and/or deficiencies in Zydus's ANDA, particularly those relating to impurity levels that required correction or further explanation in order for the FDA to grant approval of Zydus's ANDA;

d. The identity of all persons (including any third parties) involved in the drafting and preparation of Zydus's ANDA (including any amendments or supplements thereto) and/or any communications between Zydus and the FDA relating thereto, and the role that each such person had in connection therewith.

11. Any analyses performed or decisions made relating to the decision to develop the Zydus Varenicline Tartrate Products, including but not limited to:

a. The consideration of and bases for such decisions;

b. The date, timing, preparations, plans, and readiness for commercialization and launch;

c. Any market and pricing analyses, business or strategic plans, market and pricing forecasts, or sales and profit projections;

d. Any evaluation or analyses relating or referring to the impact that the launch of the Zydus Varenicline Tartrate Products on the market for varenicline tartrate products;

e. The intended market for the Zydus Varenicline Tartrate Products and any competitors to the Zydus Varenicline Tartrate Products;

f. The identity of all persons (including any third parties) involved in the above analyses and decisions, and the role that each such person had in connection therewith.

12. Business plans or projections related to the Zydus's Varenicline Tartrate Product.

13. The identity of the persons or entities (including third parties) involved in the commercial manufacture, importation, marketing, sale, and/or launch of the Zydus Varenicline Tartrate Products, and the role that each such person or entity has in those activities.

14. Any agreements, and the terms thereof, that Zydus has with any person or entity relating to:

a. the development of Zydus's Varenicline Tartrate Product;

b. the manufacture of Zydus's Varenicline Tartrate Product;

c. the supply of the active pharmaceutical ingredient used in of Zydus's Varenicline Tartrate Product,

d. the sale, distribution, importation, use or marketing of the Zydus Varenicline

Tartrate Products.

15. Zydus's awareness of the patents-in-suit, including but not limited to Zydus's first awareness of each of the patents-in-suit, and the circumstances under which Zydus first became aware of those patents.

16. Any past, current, or anticipated labeling, promotional materials, or advertising for Zydus's Varenicline Tartrate Product.

17. The inventory of Zydus's Varenicline Tartrate Product in the United States since August 2023, including the location of the inventory, number of units, and value.

18. Current or future demand for Zydus's Varenicline Tartrate Product in the United States.

19. The amount (in U.S. dollars) of sales of Zydus's Varenicline Tartrate Product in the United States.

20. Current and historic prices of Zydus's Varenicline Tartrate Product, including, but not limited to, average selling price, average wholesale price, weighted average coupon, direct price, and average market price, as well as such prices that are planned or are being considered for the future in the United States.

21. On a monthly basis from August 2023, Zydus's Varenicline Tartrate Product's unit sales, revenues, gross profit, net profit, profit margins, average unit sales price to end users, average unit sales price to distributors, list price to end users, list price to distributors, costs of goods sold, and operating costs attributed to Zydus's Varenicline Tartrate product.

22. The Zydus entity or entities responsible for U.S. sales of Zydus's Varenicline Tartrate Product.

23. Market demand for Zydus's Varenicline Tartrate Product.

24. Sales, revenue or market share forecasts for Zydus's Varenicline Tartrate Product.

25. The number of prescriptions written for Zydus's Varenicline Tartrate Product or filled with Zydus's Varenicline Tartrate Product.

26. Any patent licenses granted by or to Zydus relating to Zydus's Varenicline Tartrate Product or any patent license that Zydus contends is comparable to the term's Zydus would agree to license the patents-in-suit.

27. Any opinion, evaluation, testing, or consideration regarding the infringement, non-infringement, validity, invalidity, enforceability, unenforceability, or patentability of any claim of the patents-in-suit and Zydus's reliance thereon.

28. Any efforts by Zydus or on Zydus's behalf to investigate Par's claims of infringement of the patents-in-suit prior to initiation this case.

29. The authentication and business record status of documents produced by Zydus in this case, particularly those concerning the topics set forth in this notice.

30. The identity and location of documents concerning each of the topics in this Notice.

31. The identity and location of person(s) most knowledgeable about each of the topics in this Notice.